MICROVISK LTD

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Microvisk introduces World's First Diagnostic smart strip system in the US

CoagMax® and CoagLite® devices set for trials in major US medical centres

Microvisk Technologies has introduced its unique handheld devices which monitor the blood clotting status of patients to the US market. Showcased at the prestigious American Association for Clinical Chemistry annual conference, the Microvisk devices attracted strong interest from distributors and potential partners ahead of clinical trials in major US medical centres this autumn and product launches in 2012.

The devices branded as 'CoagMax®' and 'CoagLite®' are a point of care test and a home use test respectively that clinicians and patients can use to establish the correct dosage of anti-coagulation medication such as Warfarin and to monitor treatment. The devices are set to be trialled with 250 patients in three major cardiac centres in Florida from October with product launches scheduled for mid-2012.

Both devices incorporate a disposable SmartStrip® that uses embedded sensors to measure the clotting speed of blood from a drop of the patient's blood taken by a finger prick, with the results displayed on a handheld reader. SmartStrip is the world's first medical diagnostic strip to be based on a Micro-Electro-Mechanical System (MEMS) with an on-board memory chip and was originally created as a movement system for nano-robots. MEMS technology is used in the computer projector, iPhone and Nintendo Wii as well other technology based applications. Existing devices deploy optical analysis or measure chemical reactions, requiring a patient to provide more blood and producing a less accurate and less robust result.

Multicentre European clinical trials of CoagMax® and CoagLite® are already well under way in the UK and Germany. The devices will be introduced to the German market in November at Medica, the world's leading medical trade fair which attracts over 137,000 visitors. Product launches in both countries are scheduled for early 2012.

John Curtis, chief executive officer of Microvisk, said: "We are delighted at the overwhelming interest shown by US distributors and potential partners in our CoagMax® and CoagLite® devices – it is extremely encouraging. We remain on track to commence US clinical trials this autumn and are gearing up for product launch there in summer 2012.

"We are also continuing to make excellent progress with patient trials in the UK and Germany. We have been expanding our UK manufacturing facilities and are recruiting additional staff as we prepare for European product launches in early 2012."

Microvisk has established a US operation at Florida and recently appointed medical industry veteran, Bill Moffitt, as company chairman. Mr Moffitt has over 30 years experience in the diagnostics and medical device industry and is the president and CEO of Nanosphere in the US and the chairman of Glysure in the UK.

Bill Moffitt said: "The reaction to our introduction of the CoagMax® and CoagLite® devices to the US market was all that we could have wished for. These innovative devices will transform the way that blood testing is carried out and Microvisk now has the opportunity to capture a substantial share of the market for doctor's office and home tests for Warfarin patients."

Seven million people in the western world use Warfarin and the Food and Drug Administration (FDA) estimates that over one million new patients start taking the drug every year. Patients must have regular blood tests at their doctor's surgery or hospital clinic to ensure they receive the correct dose. Warfarin is affected by

food and exercise and if the dose is too low there is a risk of blood clots forming which can result in a stroke or heart attack, while too high a dose can lead to a life threatening bleed.

The Microvisk devices enable patients to test their blood clotting ability at home, in the same way that people with diabetes test for glucose.

John Curtis added: “Our significant market opportunity in the US and Germany is driven by their healthcare systems, which have introduced payments to all at-risk Warfarin users to do weekly home blood tests, rather than having to go to the doctor or hospital clinic.”

To date, only three companies have developed a test system for blood coagulation that can be used in a doctor’s surgery and although certified for home use, market research shows that doctors feel that they are insufficiently robust and too complex for home use.

The Microvisk SmartStrip® is unique in the blood clotting diagnostic world as a solid state system that is robust and simple to use at home. It also requires far less blood than other systems, which means less pain for the user.

The coagulation status (clotting speed) of the patient is measured by tiny multi-layered paddles on the surface of the strip and a memory chip ensures the device is calibrated to provide the highest levels of accuracy, while the MEMS technology means that high volumes of the device can be manufactured at low cost.

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Editors Notes

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Photo available on request

1. Microvisk’s CoagMax® device which will enable patients on Warfarin to carry out blood tests at home.
2. Microvisk’s exhibition stand at the American Association for Clinical Chemistry conference, where the company showcased its unique handheld devices which monitor the blood clotting status of patients.

About Microvisk Technologies

Founded in 2004, Microvisk Ltd is developing medical testing devices based on Micro Electro Mechanical Sensors for the international medical market.

Initial research was carried out at the Rutherford Appleton Laboratories facility in Oxfordshire, managed by the Science and Technology Facilities Council (STFC). Microvisk was spun of STFC and is owned by private and venture capital investors who include Porton Capital, Oxford Technology Management, New Hill (Boston, USA), Midven, the Rainbow Seed Fund and Finance Wales.

Many people suffer from coagulation (blood clotting) disorders and the Microvisk technology is designed to enable patients and clinicians to monitor blood clotting ability and assist in the correct dosage of anti-coagulation medication such as Warfarin.

Microvisk's first products are the CoagMax® device, a point-of-care test and the CoagLite® device, a home use test. The devices conduct the internationally recognised Prothrombin Time or INR test by using a drop of the patient's blood taken by a finger prick. Each device is simple to use with a large display and buttons, and sized to be discreet as it can be held in the palm of a hand.

Microvisk's technology uses a different approach to the other devices and tests on the market, which use optical analysis or chemical reactions. Microvisk uses Micro Electro Mechanical Sensors (MEMS) on a disposable strip which incorporates a small cantilever to measure viscosity. The devices can test a small volume of whole blood making the test less intrusive and effectively removing the need for a laboratory. In addition, the strip has its own on-board memory to inform the handheld instrument of all manufacturing variables and under what conditions the strip has been kept since the day of its manufacture.

The Prothrombin Time or INR test works by introducing tissue factor to begin the clotting cascade which is the same series of reactions that occur when a blood vessel is ruptured. The clot changes the blood from a free flowing solution to a gel-like substance and it is this change that the sensors monitor and detect.

Microvisk's manufacturing and INR application specific research facility is located at St Asaph Business Park in North Wales. The company also has a non-application specific technology research laboratory in Chipping Warden, Northamptonshire and an operation in Florida, USA.

The Microvisk board includes: Bill Moffitt (Chairman); Fred Hallsworth (Deputy Chairman); John Curtis (CEO); Peter Whitehouse (CFO); John Mihell (NED, also Investment Executive at Finance Wales); Matthew Frohn (NED, also a Director of Oxford Technology Management Ltd) and Terry Swainbank (NED, also Investment Director at Synergis Technologies).

For more information: **www.microvisk.com**